



# Internal Quality System Audits

## Procedure

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**Document Owner:** Corporate Quality

**Author:** Klaes, Jerry

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### General Description

**Summary & Scope** The Quality Management System shall be audited at planned intervals. The frequency and extent of audit for each activity is planned and based on the status and importance of the processes, the area to be audited and the results from previous audits. This procedure provides instructions for the planning, scheduling, and conducting of internal Quality System Audits.

**Purpose:** To define audit criteria, scope, frequency and methods and to ensure an objective and impartial internal Quality Management System audit process is planned, defined and implemented. Specifically, to determine whether the Quality Management System:

1. Conforms to planned arrangements;
2. Conforms to the requirements of ISO 9001:2000;
3. Conforms to the QMS requirements established by Exabyte; and
4. Is effectively implemented and maintained

**Who Performs:** *ISO/QMS Management Representative* is responsible for:

1. Coordinating the audit activities throughout Exabyte Corporation;
2. Ensuring there are sufficiently trained auditors to meet audit program requirements;
3. Follow-up activities including the verification of action taken and the reporting of results.
4. Reporting to Top Management the status of issues arising from results.

*Internal Auditor* is responsible for:

Unless otherwise specified, all steps are completed by the Internal Auditor. The internal auditor will either be an Exabyte employee or an outside contractor experienced in conducting QMS audits. Follow-up activities to include the verification of actions taken and the reporting of verification results. Internal auditors will be suitably trained in audit techniques and applicable ISO 9001:2000 elements prior to conducting audits. At a minimum, internal auditors will enroll in an ASQ Internal Auditor Class; be familiar with ISO 9001:2000 Standard; be well-versed in Exabyte's Policies, Procedures and Business Practices; understand the Corrective and Preventive Action procedure and thoroughly understand and contribute to the continual improvement of, Exabyte's Internal Audit Program.

*Management of areas being audited:*

Shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities to include notification when verification can be conducted and assist in the verification of the actions taken and the reporting of verification results.

**Department:** All Exabyte Employees

**When to Perform:** **Specific Circumstances:**

Internal Quality System audits are conducted on a scheduled basis. The audit schedule is maintained by Corporate Quality and is published on the company Intranet (MI.002) Deviations

are allowed to the audit schedule based on business demands.

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## Requirements

### Definitions: Quality Manual

The Quality Manual (QM.001) defines the Quality management System and, in general terms, the quality policies and procedures for the company. It describes the Quality System in accordance with company policies, objectives, and the ISO 9001:2000 Standard. The Quality Manual makes reference to other documented procedures which describe quality system processes in more detail. General responsibilities for the realization of quality are defined within the Quality Manual - directly or by reference.

### Quality System

(Quality Management System, QMS) The organizational structure, responsibilities, procedures, processes and resources for implementing Total Quality Management. This definition does not include the work engaged by employees to achieve quality; Rather, it is the system within which work is done to achieve quality objectives.

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## Warnings & Precautions

### Precautions: To prevent danger and avoid errors do the following before performing this task:

Auditors shall not audit their own specific job function. If possible, they will not audit in their own department.

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## Overview of Steps

1. Corporate Quality or designee prepares an audit schedule.
2. Before each audit the auditor prepares and plans for the audit
3. The auditor coordinates the timing of the audit with the manager of the area being audited.
4. The auditor conducts the audit
5. The auditor documents and distributes audit results.
6. Audit Follow-up and Closure
7. The Quality Manager/designee updates the audit schedule, as necessary

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## Detailed Steps

### ① Corporate Quality or designee prepares an audit schedule.

#### Result:

The audit schedule covers each element/section/clause of the Quality Management System. Normally, each element is audited annually but may be more or less frequent based on the status and importance of the processes and areas to be audited, as well as the results of previous audits. The schedule indicates the date each element/section/clause is scheduled and when it was audited.

The audit schedule (MI.002) is published on the company Intranet and is available as an attachment to this procedure.

Deviations to the audit schedule are authorized based on business needs.

**2 Before each audit the auditor prepares and plans for the audit**

**Warnings/Remarks/Requirements:**

Good pre-planning and preparation will not only expedite the audit, but will result in improved credibility of the Auditor and the audit process.

**2.1 Review records of previous audits of the area/clause/section, if any exist.**

**Result:**

The review of previous audit records, previous audit checklists, etc. may help the auditor focus on areas where past concerns were identified, or to not waste time focusing on areas that have consistently demonstrated conformance or excellence. Review of these records may help the auditor in preparation of an audit checklist for the pending audit.

**2.2 Review the relevant clause/element in the ISO Standard 9001:2000, the Quality Manual and applicable Procedure(s).**

**Result:**

Look for issues in the Exabyte Policies, Procedures, and/or the ISO Standard which can be verified either through interview, or by example. This will provide objective evidence required for the audit report.

**2.3 Prepare an audit checklist of the specific areas to audit.**

**Result:**

Form FO.101 is used to create an Audit Checklist. This also serves as part of the Audit Report.

From the review in the above steps, a checklist should be generated. The checklist will also serve as a place to record the results of the audit as objective evidence.

NOTE: Previously used checklists (ref. step 2.1) may be used as a baseline. However the auditor should always review old checklists against current Policies, Procedures, and/or the ISO Standard 9001:2000 to ensure the latest requirements.

**3 The auditor coordinates the timing of the audit with the manager of the area being audited.**

**Result:**

The manager is typically notified by e-mail first, followed up with a phone call.

**Warnings/Remarks/Requirements:**

If extreme circumstances prevent a scheduled audit from occurring, the audit shall be rescheduled to occur as soon as practicable.

**3.1 Auditor identifies audit participants.**

**Result:**

The auditor should ask the manager of the area who he or she wishes to participate.

**3.2 Auditor contacts area manager or supervisor to remind them of audit.**

**Result:**

The general guideline for notification of applicable personnel (as can be reasonably anticipated) is 2 weeks prior to the desired audit date. Again, an e-mail should be sent to the manager and participants.

**3.3 Auditor and area management establish the audit timing.**

**Result:**

A specific audit day/time is established between the auditor and the anticipated audit participants (management).

**3.4 Area management notifies other personnel, as necessary.**

**Who Does It:**

Area managers are responsible for informing other personnel in their areas of upcoming audits so there will be no surprises.

**4 The auditor conducts the audit**

**4.1 Follow audit checklists.**

**Result:**

Responses to auditor questions should, as much as reasonably possible, be substantiated by objective evidence. Whenever possible, reference records so that they can be retrieved if necessary.

**4.2 Identify non-conformance ("findings") and/or Observations**

**Result:**

As the audit commences, any non-conformance (lack of objective evidence that can show compliance to the ISO 9001:2000 standard or deviations from documented policies/procedures), should be discussed and made clear, by the auditor, during the audit interview. The auditor should try to get a signature/initials on the audit checklist from the representative before writing up nonconformities (findings) on the NCR ( Non-Conformance Report), Form FO.110.

**5 The auditor documents and distributes audit results.**

**Result:**

Auditor uses Form FO.100, Internal Quality Audit Summary to record audit. Observations are recorded on this form.

**5.1 Auditor prepares a final, completed copy of the Audit Checklist(s).**

**Result:**

Non-conformances and observations should be annotated within the Audit Checklist.

**5.2 Auditor records any non-conformities on a Non-Conformance Report (NCR), form FO.110.**

**Result:**

Each unique non-conformance gets documented on a separate NCR form.

**5.3 Auditor ensures copies of NCR's are given to the Auditee.**

**5.4 Auditor distributes copies of Audit Report.**

**Result:**

The Audit summary (FO.100), completed checklist (FO.101) and any NCR's (FO.110), along with any supporting attachments, serve as the audit report.

A copy of the completed report should be made available to the Auditee. The original checklist and any attachments, and any NCR's go to the CAR Coordinator for review at CLCA.

**5.5 Department Manager (auditee) responds to the Non Conformance Report.**

**Result:**

Department Manager ensures timely response to the NCR and provides Lead Auditor with corrective action/containment, etc. data for enclosure within the NCR.

**5.6 Auditor posts Audit Report package on the secure location on the Exabyte LAN**

**Result:**

Observations are reviewed periodically during CLCA to evaluate trends

**6 Audit Follow-up and Closure**

**6.1 Audit follow-up consists of verification of corrective action measures implemented by the auditee**

**Who Does It:**

Auditor or audit team, assisted by area management who own the NCR.

**Result:**

NCR is complete and adequate.

**6.1.1 The auditor assigned is responsible to ensure that corrective action measures have been properly implemented and are effective.**

**Result:**

This verification is performed through on-site review of measures implemented, objective evidence provided to the auditor and is recorded in the NCR.

**6.1.2 Once a corrective action measure has been verified as effective and that NCR form is complete, the auditor may close out the finding.**

**Result:**

When all findings have been closed out, the Audit may be closed out by annotating the Audit Summary Report form.

**7 The Quality Manager/designee updates the audit schedule, as necessary**

**Result:**

The internal audit schedule is based upon the results of previous audits. Therefore, it may be appropriate to change the schedule following an audit. While it is desirable to audit each ISO 9001 element/section/clause at least once a year, some areas may need more or less frequent audits.

**Records**

**Internal Quality Audit Summary/Report**

**Retention Period:**

2 years

**Responsible:**

Corporate Quality

**Non-Conformance Report**

**Retention Period:**

2 years

**Responsible:**

Corporate Quality

**Attachments**

**Audit Schedule, MI.002**

ment bility	5.1 Mgmt commitment 5.3 Quality Policy 5.4.1 Quality objectives 5.5.1 Responsibility and authority 5.5.2 Management representative 5.5.3 Internal Communication 6.1 Provision Mgmt of resources 6.2.1 Human resources (General) 8.5.1 Continual improvement	Quality Policy Organization and Management Resources	Elaine Floyd	Jerry Klaes, Tom Ward	Nov.W2				
ment	5.6.1 Management Review 5.6.2 Management Review/Review Input 5.6.3 Management review/Review Output	Mgmt Review Meetings	Elaine Floyd	Jerry Klaes	Nov.W2				
ystem	4.1 Quality Management System (General Reqts) 4.2.1 Documentation requirements (General) 4.2.2 Quality manual 5.4.2 Quality mgmt system planning	Quality System Procedures Quality Planning	Scott Gemmel	Jerry Klaes	Nov.W1				
review	5.2 Customer focus 7.2 Customer-related processes	Contract Reviews, Amendments and Records, Supplier, Service and Sales	Kim Williams, Mark LaFayette	Diana McKee	Nov.W2				
ontrol/ :	5.2 Customer focus 7.2 Customer-related processes 7.3 Design and development 7.1 Planning of product realization	Engineering, Product Life Cycle, New Product Introduction, 1U, 2U, VXA-3	Jerry Klaes, Mark LaFayette	Scott Robidart Dave Harper	Nov.W3				
it control	4.2.3 Control of documents	Document and Form Approval Approval, Issuance and Changes	Chris Opseth	Mark LaFayette	.Nov.W2				
g	7.4.1 Purchasing 7.4.2 Purchasing Information	Subcontractor evaluation Verification of purchased product	Elaine Floyd	Dennis McKay	Nov.W2				
l Support	7.5.1 Control of Production and Service 7.5.3 ID and Traceability 7.5.4 Customer Property 6.2.2 Training 8.3 Control of Non-Conforming	Tech Support, Customer Returns, Phone Center, Training Records, Identification of Product	Kim Williams, Mark LaFayette	Tammy Rogge	Nov.W2				
r on	8.2.1 Monitoring and Measurement of Cust Sat 5.3 Customer Focus 7.2.1 Contract Review (Determine Req't's)	Pre-Sales, Sales and Post Sales Customer Perception and Satisfaction	Elaine Floyd	Bob Ariniello	.Nov.W3				

Internal Quality Audit Summary, Form FO.100

Lead Auditor:	Accompanied by:
Audit Date:	
Personnel Interviewed:	
<b>Narrative Survey Summary</b>	
• <b>Findings (List findings with reference to the requirements):</b>	
• <b>Observations:</b>	
• <b>Summary:</b>	
Corrective Action Request: <input type="checkbox"/> Issued; List NCR's issued:	
Auditor Signature:	Date:
Manager's Acknowledgement:	Date:
Exabyte QA Manager/Representative:	Date:
Comments:	

Internal Quality Audit Checklist, Form FO.101

Reference	Questions	Expected Response/Record	Total/ NCRs/Obs	NCR#
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				

Non-Conformance Report, Form FO.110



## Non-Conformance Report

Initiator to complete provisions 1 through 8.

1. Lead Auditor:	2a. Date Scheduled:	2b. Date Notified:	2c. Date Performed:	(To be completed by Lead Auditor, reference NCR Log.)  3. NCR No.
Additional Auditor(s):	4. Manager/Actionee:			
5. Description of Problem:				
6. Suggestion for possible action:				
7. Tentative Target Date to complete provisions 8 –15 (from Actionee or when needed):				
Actionee TO COMPLETE 8 – 15 BELOW				
8. Containment actions (short-term Corrective Action):				9. Date Completed:
10. Investigation results: - ROOT CAUSE:				(use additional sheet if needed)
11. Corrective action:				
12. Preventive Action:				
13. Manager/Actionee Signature:			14. Effective Date:	15. (Date) <input type="checkbox"/> Ready for verification
Auditor TO COMPLETE 16 – 20 BELOW				
16. Verification by:		17. <input type="checkbox"/> Acceptable <input type="checkbox"/> Unacceptable Date:		
18. Describe verification of actions taken and results. If rejected, state the reason:			19. Copy to actionee (date):	
			20. Copy CLCA (date):	

## ***Related Documents***

***The following is a list of other documents related to the current document. Changes you make to the current document may affect the documents listed.***

### **Procedure**

PR.012  
Management Review

PR.013  
Corrective and Preventive Action

## Revision History

- A:** 03/09/2000  
New Release
- B:** 09/01/2000  
Changed 2 reference from ISO 9002 to ISO 9001.  
Removed reference to the term "SOP" in 6.4 and removed SOP definition.
- C:** 02/05/2001  
Cleaned up unnecessary and non-value-added requirements related to audit report/findings paperwork and signatures.
- D:** 05/15/2002  
Converted Ecrix Procedure QA.PR.08C to an Exabyte Procedure (mostly just replaced "Ecrix" with "Exabyte", form # changes, etc.). Process is the same.
- E:** 09/13/2004  
Review; update to reflect current practices; update authorization; add new checklist and audit summary
- 11/17/2004  
Clarified responsibilities of Management and Internal Auditors; clarified training requirements; deleted redundant verbiage; highlighted "Document in Revision" status of working documents, fixed various typo's
- 11/01/2005  
Annual review for adequacy and applicability. Owner and department changed; no revision necessary, no further changes required.
- F:** 01/17/2006  
Change procedure to allow for deviation of audit schedule based on business needs.

### Revision Notes:

## **Authorization History**

### **Tom Ward**

President and CEO  
tward@exabyte.com

F

**Date Approved:**  
02/01/2006

### **Carroll Wallace**

CFO  
CWallace@exabyte.com

F

**Date Approved:**  
02/03/2006

### **Bob Ariniello**

VP, Customer Unit  
bariniello@exabyte.com

F

**Date Approved:**  
02/01/2006

### **Kelly Beavers**

VP, Invest Relations & Bus Dev  
kjb@exabyte.com

F

**Date Approved:**  
02/28/2006

### **Jerry Klaes**

VP, Quality  
jklaes@exabyte.com

F

**Date Approved:**  
02/01/2006

### **Mike Stears**

VP, Eng/Supply Chain/Quality  
mstears@exabyte.com

F

**Date Approved:**  
02/01/2006

### **Robinson, Howard**

Vice President, Materials

F

**Date Approved:**  
02/01/2006

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### **Contributing Authors**

*The following are subject matter experts who contributed to this document:*

LaFayette, Mark A.

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### **Sign-Off Approvals**

The person responsible for this document must verify accuracy and that the steps for this procedure or work instruction have been tested and validated.

\_\_\_\_\_  
Print Name & Title

\_\_\_\_\_  
Signature

\_\_\_/\_\_\_/\_\_\_  
Date

**After you have approved this document, please sign and date below.**

\_\_\_\_\_ Date \_\_\_/\_\_\_/\_\_\_  
Tom Ward, President and CEO

\_\_\_\_\_ Date \_\_\_/\_\_\_/\_\_\_  
Carroll Wallace, CFO

\_\_\_\_\_ Date \_\_\_/\_\_\_/\_\_\_  
Bob Ariniello, VP, Customer Unit

\_\_\_\_\_ Date \_\_\_/\_\_\_/\_\_\_  
Kelly Beavers, VP, Invest Relations & Bus Dev

\_\_\_\_\_ Date \_\_\_/\_\_\_/\_\_\_  
Jerry Klaes, VP, Quality

\_\_\_\_\_ Date \_\_\_/\_\_\_/\_\_\_  
Mike Stears, VP, Eng/Supply Chain/Quality

\_\_\_\_\_ Date \_\_\_/\_\_\_/\_\_\_  
Robinson, Howard, Vice President, Materials